

II. RESPONSE TO OFFICE ACTION

A. Status of the Claims

Claims 1-24 and 39 are canceled. No claims have been amended. Claims 25 – 38 are pending and under examination.

Claims 1-24, which were not limited to the preparation of human antibodies, have been canceled without prejudice, as Applicants intend to file a continuation directed to the broader subject matter. In the present case, Applicants intend to proceed with the prosecution of claims directed to human or humanized antibodies embodied by claims 25-38.

B. Claim Rejections – 35 U.S.C. §112, Second Paragraph

The Action first rejects claim 34 as indefinite under section 112, second paragraph, taking the position that the claim includes both broad and narrower elements in the Markush grouping and is thus akin to the use of “such as” which has been held to be indefinite.

Applicants respectfully traverse. The case of *Ex parte Wu*, 10 USPQ2nd 2031 (Bd. Pat. App. & Interf 1989), relied upon by the Examiner, makes it clear that it is incumbent upon the Examiner to establish that one of ordinary skill would not have been able to ascertain the metes and bounds of the claim. *Id.* at 2033. This has not been done here. All that the Examiner has stated is that the claim includes both broader and narrower “included” elements within the Markush group. We fail to see how this fact alone, even if true, would give rise to any indefiniteness in the mind of the ordinary skilled worker. We submit that the Examiner’s reliance on the “such as” cases are misplaced. The Board in *Wu* pointed out that the term “such as” in a claim that includes broader and narrower included elements is indefinite because it raises a doubt as to whether the narrower elements are intended to be “merely exemplary” or a required

further feature of the claim. *Id.* Indeed, in *Wu*, the Board found that the term “optionally” was found to be acceptable in that it was found to be clear that “optionally” meant that the specified elements were only optional and not required. In the present case, each of the elements are included in the Markush group, there are no qualifiers like “such as” or “optionally” and thus there is no question that each of the specified elements are intended to be included within the group.

For the foregoing reasons, the Examiner is requested to reconsider and withdraw the rejection. (Applicants would specifically note that by the foregoing we are not commenting on or agreeing with the Examiner’s characterization of some elements being narrow as compared to others, etc. Indeed, some of the Examiner’s characterizations appear to be in error, but a comment on this was deemed by the Applicants as not required to address the rejection.)

C. Claim Rejections -- Obviousness

The Examiner has maintained an obviousness rejection with respect to remaining claims 25-38 over Jat et al., Kano and Kanki, further in view of Green. Applicants incorporate by reference the comments in Applicant’s preceding response over the same rejections, and provide the following additional comments.

With respect to the rejection of claims 25-38, the Examiner implicitly concedes that the combination of Jat *et al.*, Kano and Kanki are insufficient to render the claims obvious. The reason for this is that each of these pieces of prior art are concerned with *murine* antibodies, as opposed to human or humanized antibodies. The Examiner relies upon Green for the proposition that Green provides a means of providing a mouse (exemplified by the so-called Xenomouse[®]) that can be employed to produce human or humanized antibodies from the mouse. We contend that the Action fails to set forth a *prima facie* rejection.

We would note, first, that the teachings of the primary references simply provide a mouse containing a transforming oncogene (as exemplified by the Immortomouse[®]), which mouse necessarily produces only *murine* antibodies, and that the secondary reference of Green, merely provides a mouse that provides human antibodies but cannot otherwise function to produce antibody-producing cells that are capable of being immortalized without forming hybridomas (exemplified by the so-called Xenomouse[®]). Thus, neither mouse alone are sufficient to achieve the subject matter of the invention. The Examiner apparently concedes this but postulates – as taught by Applicant’s specification – that it would be obvious to breed the two species to arrive at a mouse that has both properties.

For motivation, the Examiner relies upon the fact that Green teaches that the Xenomouse can be used in “established hybridoma procedures (i.e., immortalization) to produce monoclonal antibodies.” Action at p. 8. The Examiner then postulates that someone reading Green would somehow be motivated to proceed in a manner *contrary* to Green’s teaching – by crossing Green’s Xenomouse with an Immortomouse. We would note that the only method taught in Green for producing human monoclonal antibodies is to proceed through the “established hybridoma procedure” using immortalization. However, the claims at issue require that such is achieved “without forming hybridomas.” Hence, Green actually teaches away from the solution provided by the present invention. See *In re Hedges*, 228 USPQ 685, 687 (Fed. Cir. 1986) (Proceeding contrary to the accepted wisdom of the prior art is strong evidence of non-obviousness.) Indeed, we submit that the Examiner conjecture, taken out of thin air, that someone skilled in the art would be somehow be motivated by Green to proceed in a manner contrary to Green’s teaching is the worst form of hindsight analysis – an approach forbidden by the case law. *In re Dow Chemical Co.*, 5 USPQ2d 1529 (Fed. Cir. 1988).

Thus, for the foregoing reasons it is submitted that the Examiner has failed to set forth a *prima facie* case of obviousness and Applicants thus respectfully request that the rejection be withdrawn.

CONCLUSION

Applicants believe that the foregoing remarks fully respond to all outstanding matters for this application. Applicants respectfully request that the rejections of all claims be withdrawn so they may pass to issuance.

Should the Examiner desire to sustain any of the rejections discussed in relation to this Response, the courtesy of a telephonic conference between the Examiner, the Examiner's supervisor, and the undersigned attorney at 512-536-3055 is respectfully requested.


Respectfully submitted,

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